Remarks

Amendments to the claims

Claims 7, 13 and 17 have been amended to correct obvious typographical errors, and for clarity. Claims 7 and 17 have been amended to delete the phrase "contains an amino acid sequence" and "contains an acid sequence", respectively and replace this term with the phrase "is selected from the group". Claim 13 has been amended to delete an extraneous "is" from the claim. Applicants believe that it is proper for the present amendment to be entered since it corrects obvious grammatical and typographical errors, does not raise any new issues, and does not require further consideration or search.

Double Patenting Rejections

Claims 1-35 were rejected under the judicially created doctrine of nonstatutory double patenting as being obvious in view claims 1-39 of U.S. Patent No. 6,331,422 to Hubbell, et al. ("the '422 patent"), claims 1-18 of U.S. Patent No. 6,607,740 to Hubbell, et al. ("the '740 patent"), 1-5 of U.S. Patent No. 6,894,022 to Hubbell, et al. ("the '022 patent"), and claims 1-34 of co-pending application No. 10/325501. Claims 1-35 were provisionally rejected under the judicially created doctrine of nonstatutory double patenting as being obvious in view claims 1-25 of co-pending application No. 10/323046 by Hubbell, et al. ("the '046 application") Claims Applicants respectfully traverse these rejections.

Legal Standard

Double patenting results when the right to exclude granted by a first patent is unjustly extended by the grant of a later issued patent. *In re Van Ornum*, 214 U.S.P.Q. 761 (C.C.P.A. 1982); *In re Zickendraht*, 138 U.S.P.Q. 22 (C.C.P.A. 1963) (Rich, J., concurring). It is clear that this situation can only arise if there is common ownership.

Both 37 C.F.R. and 35 U.S.C. makes clear the necessity for common ownership; the MPEP affirms this requirement.

37 C.F.R. 1.78(d) provides "Where an application claims an invention which is not patentably distinct from an invention claimed **in a commonly owned patent with the same or a different inventive entity**, a double patenting rejection will be made in the application. An obviousness-type double patenting rejection may be obviated by filing a terminal disclaimer in accordance with § 1.321(b)."

37 C.F.R § 1.321(c)(3) requires that "a terminal disclaimer filed to obviate a judicially created double patenting rejection in a patent application... must...include a provision that any patent granted on that application...shall be enforceable only for and during such period that said patent is **commonly owned** with the application or patent which formed the basis for the rejection." (emphasis added).

The present application and the patents forming the basis of the present rejection are not commonly owned. Therefore, a terminal disclaimer is neither appropriate nor allowed under the patent rules.

There is only one exception to the requirement for common ownership, **where there is a joint research agreement, which is not applicable here.** The examiner's attention is drawn to MPEP 804 which states in relevant part:

Before consideration can be given to the issue of double patenting, two or more patents or applications

(1) must have at least one common inventor

and/or be either

(2)

(a) commonly assigned/owned

or

(b) non-commonly assigned/owned but subject to a joint research agreement as set forth in 35 U.S.C. 103(c)(2) and (3) pursuant to the CREATE Act (Pub. L. 108-453, 118 Stat. 3596 (2004)). (numbering added)

Accordingly, it is clear that this rejection is legally improper with respect to U.S. Patent No. 6,894,022 to Hubbell et al., U.S.S.N. 10/325,021, now U.S. Patent No. 7,247,609 to Hubbell, et al. and copending application No. 10/323046 by Hubbell, et al., which do not share common ownership with the present application. Thus the claims should only be rejected under 35 U.S.C. §102 and/or §103, discussed below.

(a) U.S. Patent No. 6,331,422 to Hubbell, et al. ("the '422 patent")

Claims 1-35 were rejected under the judicially created doctrine of nonstatutory double patenting as being obvious in view claims 1-39 of the '422 patent. Applicants will submit a terminal disclaimer without prejudice to overcome this double patenting rejection when the claims are determined to be otherwise patentable.

(b) U.S. Patent No. 6,607,740 to Hubbell, et al. ("the '740 patent")

Claims 1-35 were rejected under the judicially created doctrine of nonstatutory double patenting as being obvious in view claims 1-18 of the '740 patent. Applicants will submit a terminal disclaimer without prejudice to overcome this double patenting rejection when the claims are determined to be otherwise patentable.

(c) U.S. Patent No. 6,894,022 to Hubbell, et al. ("the '022 patent")

Claims 1-35 were rejected under the judicially created doctrine of nonstatutory double patenting as being obvious in view claims 1-5 of U.S. Patent No. 6,894,022 to Hubbell, et al. ("the '022 patent"). Applicants respectfully traverse this rejection for the reasons set forth below.

The '022 patent is jointly owned by Eidgenössische Technische Hochschule Zürich and Universität Zürich. The pending application is owned by California Institute of Technology. Thus the '022 patent and the pending application are not commonly owned. Additionally, the '022 patent and the pending application are not subject to a joint research agreement. Therefore the rejection for obviousness-type double patenting over claims 1-5 of the '022 patent is an

improper rejection. As stated above, the claims in the present application should only be rejected under §102 and/or §103. Even is such a rejection were made, the '022 patent do not anticipate or make obvious the present claims for at least the reasons listed below.

The '022 patent does not anticipate the present claims

As stated in the amendment and response filed on December 29, 2006, claims 1-5, 10-14, 18-22 and 28-30 are fully supported by priority application, U.S.S.N. 09/057,052 filed April 8, 1998, which is before the earliest priority date for the '022 patent, *i.e.* August 27, 1998. Therefore, the '022 patent cannot anticipate claims 1-5, 10-14, 18-22 and 28-30. Similarly, as acknowledged by the Examiner's withdrawal of the rejection of claims 7, 9, 16, 17, 26, 27, 34 and 35 under §102(e) in view of the '022 patent, claims 7, 9, 16, 17, 26, 34 and 35 are not anticipated by the '022 patent.

The '022 patent does not render the present claims obvious

The scope and content of the '022 patent claims relative to claims 1-5, 7, 9-14, 16-22, 26-30, 34, and 35 of the present application

<u>*The Claims in the present application*</u>

(a) Composition claims

Claims 1-5, 7 and 9 define a composition comprising a matrix and a bidomain protein or peptide having an amino acid sequence that comprises a transglutaminase substrate domain and a polypeptide growth factor, wherein the protein or peptide is covalently bound to the matrix by the transglutaminase substrate domain.

(b) Method claims

Claims 10-14 and 16-17 define a method of attaching a polypeptide growth factor to a matrix, comprising producing a bidomain peptide or protein comprising a growth factor and a transglutaminase substrate domain; and exposing the matrix to a transglutaminase to covalently couple the bidomain peptide or protein to the matrix and crosslink the matrix.

(c) Product claims

(i) Claims 18-22, 26, and 27 define a bidomain protein or peptide comprising a transglutaminase substrate domain and a polypeptide growth factor.

(ii) Claims 28-30, 34, and 35 define a matrix material for forming a gel comprising (i) a bidomain protein or peptide comprising a transglutaminase domain and a polypeptide growth factor, (ii) fibrinogen, (iii) factor XIIIa, and (iv) thrombin.

Claims 1-5 of the '022 patent

1. An engineered protein or polysaccharide comprising at least one first domain comprising heparin or heparin-like peptides, and a second attachment domain, wherein the second domain is a substrate domain for a crosslinking enzyme, and wherein the engineered protein or polysaccharide is covalently attachable to a matrix through the second attachment domain.

2. The engineered protein or polysaccharide of claim 1, wherein the second attachment domain comprises a transglutaminase substrate domain.

3. An engineered protein or polysaccharide comprising at least one first domain comprising heparin or heparin-like peptides, and a second attachment domain, and a cleavage site between the first domain and the second attachment domain, wherein the engineered protein or polysaccharide is covalently attachable to a matrix through the second attachment domain.

4. The engineered protein or polysaccharide of claim 3, wherein the cleavage site is an enzymatic cleavage site, which is cleaved by an enzyme selected from the group consisting of plasmin and matrix metalloproteinase.

5. The engineered protein or polysaccharide of claim 2 wherein the second attachment domains is a Factor XIIIa substrate domain.

The differences between claims 1-5 of the '022 patent and claims 1-5, 7, 9-14, 16-22, 26-30, 34, and 35.

Claims 1-5, 7 and 9

Claims 1-5 of the '022 patent do not recite all of the elements of the claims

As stated above, claims 1-5 of the '022 patent do not anticipate claims 1-5, 7 and 9 of the present application; the '022 patent is not available as prior art with respect to claims 1-5, therefore, claims 1-5 of the '022 patent cannot make the present claims 1-5 obvious. With respect to claims 7 and 9, for at least the reasons stated above with respect to anticipation, claims 1-5 of the '022 patent do not recited all of the limitations of claims 7 and 9. There is no disclosure of a bidomain protein, let alone a bidomain protein containing the growth factors in the compositions defined by claims 7 and 9.

Furthermore, there is no motivation for one of ordinary skill in the art to modify the engineered protein-which is a peptide/polysaccharide chimera, (i.e. not containing a full length protein, *see* the '022 patent, col. 5, lines 65-66, col. 7, lines 45-52 and col. 7, lines 5-11) defined by claims 1-5 of the '022 patent to arrive at the composition defined by claims 7 and 9.

Therefore, claims 1-5 of the '022 patent do not make obvious claims 1-5, 7, and 9 of the present application.

Claims 10-14 and 16-17

Claims 1-5 of the '022 patent do not recite all of the elements of the claims

Claims 10-14 and 16-17 define a method of attaching a polypeptide growth factor to a matrix, comprising producing a bidomain peptide or protein comprising a growth factor and a transglutaminase substrate domain; and exposing the matrix to a transglutaminase to covalently couple the bidomain peptide or protein to the matrix and crosslink the matrix. Claims 1-5 of the '022 patent define and engineered protein or polysaccharide.

As stated above, claims 1-5 of the '022 patent do not anticipate claims 10-14 and 16-17 of the present application; the '022 patent is not available as prior art with respect to claims 10-14, therefore, claims 1-5 of the '022 patent cannot make the present claims 10-14 obvious. For at least the reasons stated above with respect to anticipation, claims 1-5 of the '022 patent do not recite all of the limitations of claims 16 and 17. Furthermore, one of ordinary skill in the art cannot extrapolate from claims 1-5 of the '022 patent, to arrive at the method defined by claims

16 and 17. Therefore, claims 1-5 of the '022 patent do not make obvious claims 10-14 and 16-17 of the present application.

Claims 18-22, 26 and 27

Claims 1-5 of the '022 patent do not recite all of the elements of the claims

As stated above, claims 1-5 of the '022 patent do not anticipate claims 18-22 and 26-27; the '022 patent is not available as prior art with respect to claims 18-22, therefore, claims 1-5 of the '022 patent cannot make obvious claims 18-22. For at least the reasons stated above with respect to anticipation, claims 1-5 of the '022 patent do not recite all of the limitations of claims 26 and 27. There is nothing in the '022 patent that would lead one of ordinary skill in the art to substitute the peptide chimera (*see* the '022 patent, col. 5, lines 65-66, col. 7, lines 45-52 and col. 7, lines 5-11) with a full length protein to arrive at the claimed bidomain peptide. Therefore, claims 1-5 of the '022 patent do not make obvious claims 18-22, 26, and 27 of the present application.

Claims 28-30, 34, and 35

Claims 1-5 of the '022 patent do not recite all of the elements of the claims

Claims 1-5 of the '022 patent do not anticipate the matrix defined by claims 28-30, 34, and 35; the '022 patent is not prior art with respect to claims 28-30 and therefore cannot make obvious claims 28-30. Also, for at least the reasons stated with respect to anticipation, claims 1-5 of the '022 patent do not recite all of the limitations of claims 34 and 35. The Examiner has provided no reason why one of ordinary skill in the art would extrapolate from the engineered

protein or polysaccharide defined by claims 1-5 of the '022 patent to arrive at the matrix defined by claims 34 and 35. Therefore, claims 1-5 of the '022 patent do not make obvious claims 28-30, 34, and 35 of the present application.

(d) Application No. 10/325,501

Claims 1-35 were rejected under the judicially created doctrine of nonstatutory double patenting as being obvious in view claims 1-34 of co-pending application No. 10/325,501. The office action refers to claims 1-34 of U.S.S.N. 10/325,501. However, this appears to be a typographical error as U.S.S.N. 10/325,501 is an issued patent, U.S. Patent No. 6,704,685, entitled "*Method And Device For Determining The Signal Running Time Between A Position Measuring System And A Processing Unit*". Therefore, Applicants have treated the provisional rejection as if it was made over claims 1-20 of U.S.S.N. 10/325,021, now U.S. Patent No. 7,247,609 ("the '609 patent").

The '609 patent is jointly owned by Eidgenössische Technische Hochschule Zürich and Universität Zürich. The pending application is owned by California Institute of Technology. Thus the '609 patent and the pending application are not commonly owned. Additionally, the '609 patent and the pending application are not subject to a joint research agreement. Therefore the rejection for obviousness-type double patenting over claims 1-20 of the '609 patent is an improper rejection. As stated above, the claims in the present application could only be rejected under §102 and/or §103. Even is such a rejection were made, the '609 patent does not anticipate or make obvious the present claims for at least the reasons listed below.

The '609 patent is not available as prior art

The '609 patent is a continuation-in-part of application No. 10/323,046 filed on December 17, 2002, and a continuation-in-part of application No. 10/024,918, filed on December 18, 2001, now abandoned. Claims 1-5, 10-14, 18-22, and 28-30 of the present application are fully supported by priority application, U.S.S.N. 09/057,052, filed April 8, 1998. Therefore, these claims cannot be anticipated or made obvious by claims 1-39 of the '609 patent. Claims 7, 9, 16, 17, 26, 27, 34, and 35, these claims are fully supported by priority application, U.S.S.N. 10/024,918 filed on December 18, 2001. Thus, the '609 patent is not available as prior art against the claims of the present application under 35 U.S.C. §102 and/or §103. For at least the reasons set forth above, the '609 patent does not anticipate or make obvious claims 1-5, 7, 9-14, 16-22, 26-30, 34, and 35 of the present application.

(e) Co-pending application No. 10/323,046 by Hubbell, et al. (the '046 application)

Claims 1-35 were provisionally rejected under the judicially created doctrine of nonstatutory double patenting as being obvious in view claims 1-25 of the '046 application.

The '046 application is jointly owned by Eidgenössische Technische Hochschule Zürich and Universität Zürich. The present application is owned by California Institute of Technology. Thus the ''046 application and the present application are not commonly owned. Additionally, the '046 application and the present application are not subject to a joint research agreement. Therefore the rejection for obviousness-type double patenting over claims 1-35 of the '046 application is an improper rejection. As stated above, the claims in the present application could

only be rejected under §102 and/or §103. Even is such a rejection were made, the '046 application does not anticipate or make obvious the present claims for at least the reasons listed below.

Co-pending application No. 10/323,046 is a continuation-in-part of the '022 patent. Thus, for reasons set for the with respect to the '022 patent, claims 1-5, 10-14, 18-22, and 28-30 are not anticipated or made obvious by claims 1-35 of the '046 application. Similarly, the '046 application does not anticipate or make obvious claims 7, 9, 16, 17, 26, 27, 34, and 35 of the pending application.

Entry of the amendment to the claims is respectfully solicited.

Allowance of claims 1-5, 7, 9-14, 16-22, 26-30, 34, and 35, as amended, is respectfully solicited.

Respectfully submitted,

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